REMARKS

Reconsideration of the present application in view of the present amendments and the following remarks is respectfully requested. Claims 42, 44-52, and 56-57 are pending and currently under consideration. Previously withdrawn claim 101 is hereby cancelled without prejudice to further prosecution of the subject matter in a related divisional, continuation, or continuation-in-part application. Applicants have amended claims 42, 47, and 51 to particularly point out and distinctly claim the subject matter encompassed by Applicants' invention. Support for the amended claims may be found in the specification, for example, at page 18, lines 1-6; page 19, lines 19-27; and the Sequence Listing. No new matter has been added.

REJECTIONS UNDER 35 U.S.C. § 102(b)

The PTO rejects claims 42, 44, 45, and 46 under 35 U.S.C. § 102(b) as anticipated by Rojo and Walliman (*Biochim. Biophys. Acta* 1187:360-67 (1994)). The PTO alleges that bovine ANT as disclosed by Rojo and Walliman is 98% homologous to SEQ ID NO:33 of the instant application. The PTO also asserts that the cited document teaches that the bovine ANT protein disclosed therein is capable of binding to an ANT ligand, has been separated from other proteins, and would not contain any human ANT polypeptides. The PTO further asserts that ANT3 is expressed in all tissues and has the same molecular weight as the isolated protein described in Rojo and Walliman.

Applicants respectfully traverse this rejection and submit that the cited document fails to destroy the novelty of the present claims. The present invention is directed, in pertinent part, to an isolated recombinant human ANT polypeptide comprising the amino acid sequence of a human ANT3 polypeptide set forth in SEQ ID NO:33, wherein the recombinant human ANT polypeptide is capable of binding an ANT ligand and is produced by culturing a host cell that comprises a recombinant expression construct having at least one regulated promoter operably linked to a nucleic acid encoding the ANT3 polypeptide.

Rojo and Walliman fail to anticipate each and every limitation of the present claims. The cited document fails to teach or suggest a human recombinant ANT polypeptide that comprises the human ANT3 polypeptide sequence set forth in SEQ ID NO:33. The document

also fails to teach or suggest that the recombinant ANT3 polypeptide is produced by culturing a host cell comprising a recombinant expression construct that comprises at least one regulated promoter. Rojo and Walliman describe purification of ADP/ATP carrier (AAC) polypeptides from *non-human* animal tissues and fail to teach or suggest an amino acid sequence of any isolated polypeptide.

Accordingly, Applicants respectfully submit that the cited document fails to destroy the novelty of the claimed isolated recombinant human ANT polypeptides.

The PTO also rejects claims 42, 45, and 46 under 35 U.S.C. § 102(b) as anticipated by Miroux et al. (*J. Mol. Biol.* 260:289-98 (1996)). The PTO alleges that the protein disclosed in Miroux et al. is indistinguishable from an ANT protein that is at least 95% identical to SEQ ID NO:33 and is capable of binding an ANT ligand.

Applicants respectfully traverse this rejection and submit that the cited document fails to anticipate each and every limitation of the claimed polypeptide. Miroux et al. fail to teach or suggest a human recombinant ANT polypeptide that comprises the human ANT3 polypeptide sequence set forth in SEQ ID NO:33. The cited document further fails to teach or suggest any polypeptide sequence.

Miroux et al. describe a bovine ANT polypeptide that can be measurably expressed in *E. coli* in the form of an inclusion body; however, contrary to the assertion in the Action, Miroux et al. fail to teach or suggest that the bovine ANT polypeptide in the inclusion body is capable of binding to an ANT ligand. As understood in the art and acknowledged by the PTO, renaturation and reconstitution of ANT polypeptides from inclusion bodies pose a significant challenge that the art had failed to overcome at the time of filing the instant application, and even well afterwards (Action, page 3, citing Heimpel et al. (*J. Biol. Chem.* 276:114499-506 (2001)). Moreover, the PTO points out in an Office Action in a related application that Miroux et al. show expression of recombinant ANT in *E. coli*; "however, it appears that the expressed ANT accumulates in inclusion bodies where it is unfolded and inactive." (See Action, U.S.A.N. 09/811,131, dated February 2, 2004, page 9-10.) Therefore, an ANT polypeptide in an inclusion body lacks the capability, that is, the potential, to bind to a

ligand because such an ANT polypeptide *cannot* be readily reconstituted into a properly folded form. Applicants therefore submit that Miroux et al. fail to anticipate the claimed subject matter.

Accordingly, Applicants respectfully submit that the present invention satisfies the requirements for novelty under 35 U.S.C. § 102(b) and request that these rejections be withdrawn.

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (WRITTEN DESCRIPTION)

The PTO rejects claims 42, 44-52, and 56-57 under 35 U.S.C. § 112, first paragraph, asserting that the claims are directed to subject matter that is not adequately described in the specification. More specifically, the Action asserts that (1) non-human sequences are known that are greater than 95% identical to SEQ ID NO:33; (2) the specification provides only one species of the genus; (3) all human ANT sequences are not presently known; and (4) the specification has not provided sufficient written description as to what sequences are considered human.

Applicants respectfully traverse these grounds of rejection and submit that Applicants possessed the claimed invention at the time the Application was filed. As described in the specification and recited in the instant claims, the invention relates to an isolated recombinant human ANT polypeptide comprising the amino acid sequence of a human ANT3 polypeptide set forth in SEQ ID NO:33 that is capable of binding an ANT ligand, and that is produced by a method comprising culturing a host cell that comprises a recombinant expression as recited, and to related compositions (*see, e.g.,* page 14, lines 17-28; page 15, line 19-28; page 22, line 22 through page 27; Examples 1-5). Therefore, and as the PTO concedes (Action, page 7, lines 12-13), the specification reasonably conveys to a skilled artisan that Applicants possessed the claimed recombinant human ANT polypeptide comprising the amino acid sequence of a human ANT3 polypeptide set forth in SEQ ID NO:33, at the time the Application was filed.

Applicants therefore submit that the instant Application complies with the written description requirement under 35 U.S.C. § 112, first paragraph, and respectfully request that the rejection be withdrawn.

Applicants respectfully submit that all claims in the Application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. In the event that the Examiner believes a teleconference will facilitate prosecution of this case, the Examiner is invited to telephone the undersigned representative at (206) 622-4900.

Respectfully submitted,

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